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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TURNER, SHARON L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,288

Applicant(s)

SCHENK ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50,69,70 and 73-98 is/are pending in the application.
- 4a) Of the above claim(s) 50,69,70,73-86 and 90-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 50,69,70 and 73-98 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Response to Amendment

1. The amendment filed 5-12-03 has been entered into the record and has been fully considered.
2. Claims 1-49, 51-68 and 71-72 are canceled. Claims 50, 69-70, 73-98 are pending.
3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.
5. Newly submitted claims 50, 69-70 and 73-86 and 90-98 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly amended claims 50, 69-70, 73-80 and 89 are newly drawn to clearing tissue samples, newly amended claims 81-86 are newly drawn to clearing isolated biological entities, and newly amended claims 90-97 are newly drawn to clearing amyloid deposits. Each of the three different groups of claims are distinct as set forth comprising different reagents, steps and outcomes including different cells, organisms, viruses, antigens and antibodies. All new methods are distinct in recitation as to the previous claims.

Since applicant has received an action on the merits for the originally presented invention, these inventions have been constructively elected by original presentation for prosecution on the merits. Accordingly, the claims are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 87-89 stands rejected under 35 U.S.C. 102(b) as being anticipated by Jorbeck et al., Infection & Immunity, 32(2):497-502, May 1981.

Jorbeck et al., teach the analysis of the specificity and activity of antibodies generated against different *Salmonella* antigens. The analysis is via in vitro phagocytosis assays measuring the ability of activated peritoneal exudates cells (PEC) to phagocytose and control of the growth of *Salmonella*, see in particular abstract and p. 497, paragraph spanning columns 1-2. The in vitro phagocytosis assays are described

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at p. 498 columns 1-2. The in vitro assays involve combination of PEC exudates containing polymorphonuclear leukocytes, lymphocytes and monocytes-macrophages (phagocytic cells bearing Fc receptors), with pre- or post-vaccination serum (containing antibodies), *Salmonella* (antigen/biological entity) and monitoring clearance of *Salmonella* bacteria via phagocytosis (antigen/biological entity). The results of the various antibodies in effecting clearance in vitro and in vivo are shown at pp. 498-502, Figures 2-3 and Tables 1-4. The in vitro analysis is deemed to be in tissue in that the cells are an aggregate of similarly specialized cells that are united in the performance of a particular function. Here the PEC exudates are involved in the lysis of *Salmonella*. Thus the reference teachings anticipate the claimed invention wherein the antigen is the biological entity (*Salmonella* bacteria) and wherein the antigen is in physical association with the biological entity, i.e., it is a part of the bacteria (biological entity).

Applicant's argument in the response of 5-12-03 that Jorbeck does not apply to the amended claims as the claims are directed to a tissue sample. Applicant's argument that *Salmonella* is not a tissue sample or a biological entity physically associated with an antigen and thus that Jorbeck does not apply.

Applicant's arguments filed 5-12-03 have been fully considered but are not persuasive. The PEC exudates and *Salmonella* are indeed biological entities physically associated with an antigen. Further the in vitro assays are deemed to be in tissue in that the PEC exudates are aggregates of specialized cells that perform the lytic function. Thus, Jorbeck applies to the new claims in that the analysis is in vitro in tissue and the PEC exudates and *Salmonella* are biological entities physically associated with

an antigen. Thus, the reference teachings anticipate the claimed invention.

8. Claims 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Vitek et al., US Patent No. 5,935,927.

Vitek et al., teach compositions and methods for stimulating amyloid removal in amyloidogenic diseases using advanced glycosylation endproducts. In particular the method includes stimulating mechanisms of recognition and removal of AGE-amyloid in an animal to remove the amyloid plaques via scavenger systems such as phagocytic cells, macrophages and in neural tissue microglial cells, see in particular column 6, line 36-column 7, line 33. A particular embodiment of the invention includes wherein the therapeutic agents include antibodies to AGE-amyloid, in particular antibodies to AGE-beta amyloid, see in particular column 7, lines 11-16, column 12, lines 46-67, column 15, column 16, lines 44-52. In addition, Vitek teaches where the effectiveness of an AGE bearing targeting agent can be tested for efficacy, see in particular column 21-22, paragraph spanning and column 24, lines 13-25, including the use of in vitro and in vivo assays, see in particular column 22, line 54-column 23, line 14. In particular assays the method provides for combination of anti-AGE antibody, various antigens including beta amyloid antigen and culture with phagocytic cells, including microglia with monitoring of the amount of AGE modified protein/antigen/biological entity amongst samples and over time. The antibodies of Vitek include monoclonal antibodies, see in particular column 15, lines 26-58. The assays may be in vitro and in biological tissue, particularly where the tissue is from the brain of an animal having amyloid plaques or Alzheimer's pathology. In the Vitek assays the antigen AGE, for example is a physical modification

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of beta amyloid and may or may not be present on the beta amyloid biological entity. Nevertheless, Vitek contemplates where the antigen is either present or absent from beta amyloid (the biological entity) and thus Vitek's teachings would encompass either interpretation of whether or not both antigen and entity are required to be in contact with antibody and phagocytic cells. The assays for monitoring the effectiveness in clearance would yield information pertaining to the different antibody agents used for treatment or clearance of plaques and thus the assays necessarily recognizes the ability to distinguish the activity of particular agents (antibodies) in mediating AGE, amyloid or AGE plaque clearance. Animal tissue comprises inflammatory cells and Alzheimer's plaques are considered nonmalignant abnormal cell growth. Moreover, the in vitro analysis may be in tissue sections viewed and fixed via microscopy on microscope slides as disclosed at column 32 Example 2. Thus, the reference teachings anticipate the claimed invention directed to clearance of an antigen-associated biological entity as set forth above.

Applicants argue in the response of 5-13-02 that Vitek does not apply to the amended claims as directed to assays in vitro. Further applicant's argue that the method is designed to screen AGE-thioflavin for capacity to modify insoluble or aggregated beta amyloid and that the combination would not logically be performed in the presence of phagocytic cells.

Applicant's arguments filed 5-13-02 have been fully considered but are not persuasive. Vitek et al., disclose suitable assays in vitro for the analysis of target agents that promote the clearance of amyloid plaques. The reference includes where

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the agents are antibodies and the antibodies are used to clear plaques. The tissue samples use phagocytic cells and/or provide them where absent, note as set forth above. While Vitek references a particular ELISA assay with thioflavin, the reference teachings are not limited to this particular assay that applicants argue are a measure of soluble or insoluble amyloid. Such an assay does not negate the references cumulative teachings as to assays to detect clearance of amyloid plaques. Thus, the rejection is maintained.

Status of Claims

9. No claims are allowed.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
September 4, 2003


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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